

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Previously presented) Aerosol composition comprising a propellant and contained therein a first particulate material comprising particles having a median aerodynamic diameter within the range 0.05 μm to 11 μm and a second particulate material comprising particles having a median volume diameter within the range 15 to 200 μm , wherein the first and second particulate materials are segregated upon aerosolization into a respirable first fraction and a non-respirable second fraction.
2. (Previously presented) Composition according to claim 1 wherein the second particulate material has a median volume diameter within the range 20 to 125 μm .
3. (Previously presented) Composition according to claim 1 wherein the weight ratio of first particulate material to second particulate material in the composition lies in the range 1:0.1 to 1:500.
4. (Previously presented) Composition according to claim 3 wherein the weight ratio of first particulate material to second particulate material in the composition lies in the range 1:10 to 1:100.
5. (Previously presented) Composition according to claim 1 wherein the first particulate material has a median aerodynamic diameter within the range 1 to 10 μm .
6. (Previously presented) Composition according to claim 1 wherein the second particulate material has a Mohs hardness value of less than 5.

7. (Previously presented) Composition according to claim 1 wherein the second particulate material has a Carr Index value:
- for particles more than 100 um in size of less than 14%;
- for particles 40 to 100 um in size of less than 28%;
- for particles 20 to 40 um in size of less than 35%; and
- for particles less than 20 um in size of less than 65%.
8. (Previously presented) Composition according to claim 1 wherein the solubility of the first particulate material in the propellant is less than 49.9 wt% with respect to the total weight of the substance present in the composition comprising the first particulate material.
9. (Previously presented) Composition according to claim 1 wherein the solubility of the second particulate material in the propellant is less than 49.9 wt% with respect to the total weight of the substance present in the composition comprising the second particulate material.
10. (Previously presented) Composition according to claim 1 wherein the composition comprises at least 80 wt% and up to 99.999 wt% propellant.
11. (Currently amended) Composition according to claim 10 wherein the total of the first and second particulate material [composition] comprises at least 0.001 wt% and up to 20 wt% of the composition [first and second particulate material present].

12. (Previously presented) Composition according to claim 1 further comprising a surfactant, flavouring material, buffer, preservative or any mixture thereof.
13. (Previously presented) Composition according to claim 1 wherein the propellant is selected from the group consisting of chlorofluorocarbons, hydrofluorocarbons, and mixtures thereof.
14. (Previously presented) Composition according to claim 13 wherein the propellant is selected from the group consisting of hydrofluorocarbons and mixtures thereof.
15. (Previously presented) Composition according to claim 14 wherein the propellant is a hydrofluoroalkane selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, and mixtures thereof.
16. (Canceled)
17. (Canceled)
18. (Previously presented) Composition according to claim 1 wherein the first particulate material is a medicament.
19. (Previously presented) Composition according to claim 18 wherein the medicament is selected from the group consisting of salbutamol, salbutamol sulphate, terbutaline, terbutaline sulphate, ipratropium bromide or any physiologically acceptable salts or solvates thereof; beclomethasone dipropionate, budesonide, triamcinolone acetonide or any physiologically acceptable solvates thereof;

corticosteroid, bronchodilator; peptides, proteins, nucleic acids or derivatives thereof; insulin, calcitonin, growth hormone, lutensing hormone releasing hormone, leuprolide, and oxytocin or any physiologically acceptable salts or solvates thereof, and any mixture thereof.

20. (Currently amended) Composition according to claim 18 wherein the medicament is salmeterol xinafoate or [any mixture thereof] a mixture of salmeterol xinafoate with any one of the group consisting of salbutamol, salbutamol sulphate, terbutaline, terbutaline sulphate, ipratropium bromide or any physiologically acceptable salts or solvates thereof; beclomethasone dipropionate, budesonide, triamcinolone acetonide or any physiologically acceptable solvates thereof; corticosteroid, bronchodilator; peptides, proteins, nucleic acids or derivatives thereof; insulin, calcitonin, growth hormone, lutensing hormone releasing hormone, leuprolide, and oxytocin or any physiologically acceptable salts or solvates thereof, and any mixture thereof.
21. (Previously presented) Composition according to claim 19 wherein the medicament is salbutamol sulphate.
22. (Currently amended) Composition according to claim 18 wherein the medicament is fluticasone propionate or [any mixture thereof] a mixture of fluticasone propionate with any one of the group consisting of salbutamol, salbutamol sulphate, terbutaline, terbutaline sulphate, ipratropium bromide or any physiologically acceptable salts or solvates thereof; beclomethasone dipropionate, budesonide, triamcinolone acetonide or any physiologically acceptable solvates

thereof; corticosteroid, bronchodilator; peptides, proteins, nucleic acids or derivatives thereof; insulin, calcitonin, growth hormone, lutensing hormone releasing hormone, leuprolide, and oxytocin or any physiologically acceptable salts or solvates thereof, and any mixture thereof.

23. (Previously presented) Composition according to claim 18 wherein the medicament is beclomethasone dipropionate or a physiologically acceptable solvate thereof, or any mixture thereof with any one of the group consisting of salbutamol, salbutamol sulphate, terbutaline, terbutaline sulphate, ipratropium bromide or any physiologically acceptable salts or solvates thereof; beclomethasone dipropionate, budesonide, triamcinolone acetonide or any physiologically acceptable solvates thereof; corticosteroid, bronchodilator; peptides, proteins, nucleic acids or derivatives thereof; insulin, calcitonin, growth hormone, lutensing hormone releasing hormone, leuprolide, and oxytocin or any physiologically acceptable salts or solvates thereof, and any mixture thereof.
24. (Currently amended) Pharmaceutical composition comprising a propellant and contained therein a particulate medicament comprising particles having a median aerodynamic diameter within the range 0.05 to 11 μm and a second particulate material comprising particles having a median volume diameter within the range 15 to 200 μm , wherein the second particulate material is selected from the group consisting of amino acids, di-, tri-, oligo-, and poly-peptides, proteins, physiologically acceptable derivatives, forms, salts, and solvates thereof, and mixtures thereof, and wherein the

particulate medicament and second particulate materials are segregated upon aerosolization into a respirable first fraction and a non-respirable second fraction.

25. (Original) A container containing a composition according to any one of the preceding claims wherein the container includes a valve outlet.
26. (Previously presented) A container according to claim 25 wherein the valve outlet is a metered dose valve.
27. (Previously presented) An inhalation device incorporating a container according to claim 25.
28. (Original) A container according to claim 26 in the form of a metered dose inhaler.
29. (Original) A method for preparing an aerosol composition according to any one of claims 1 to 24 comprising:
- (a) forming a mixture of the first particulate material and the second particulate material;
 - (b) dispensing measured portions of respectively the said mixture and the propellant into a container; and
 - (c) sealing the container.
30. (Original) The method according to claim 29 wherein the mixture is dispensed into the container before the propellant.

31. (Previously presented) A method for preparing a composition according to any one of claims 1 to 24 comprising admixing the ingredients together prior to dispensing into a container and sealing the container.
32. (Previously presented) The method according to claim 31 wherein the container includes an outlet valve.
33. (Currently amended) A mixture of first particulate material having a median aerodynamic diameter within the range 0.05 to 11 μm and a second particulate material having a median volume diameter within the range of 15 to 200 μm , wherein the second particulate material is selected from the group consisting of amino acids, di-, tri-, oligo-, and poly-peptides, proteins, physiologically acceptable derivatives, forms, salts, and solvates thereof, and mixtures thereof, and wherein the first and second particulate materials are segregated upon aerosolization into a respirable first fraction and a non-respirable second fraction.
34. (Original) A method of administering a particulate medicament to a patient in need thereof comprising forming an aerosol from the aerosol composition according to any one of claims 18 to 24 and the patient inhaling the aerosol.
35. (Original) An aerosol composition according to any one of claims 18 to 24 for use in the treatment of respiratory disorders.
36. (Canceled)
37. (Canceled)

38. (Previously presented) Composition of claim 1 wherein the second particulate material is selected from the group consisting of amino acids, di-, tri-, oligo-, and poly-peptides, proteins, physiologically acceptable derivatives, forms, salts, and solvates thereof, and mixtures thereof.
39. (Previously presented) Aerosol composition comprising a propellant and contained therein a first particulate material comprising particles having a median aerodynamic diameter within the range 0.05 μm to 11 μm and a second particulate material comprising particles having a median volume diameter within the range 38 to 200 μm .
40. (Previously presented) Composition of claim 39, wherein the second particulate material is a carbohydrate.
41. (Previously presented) Composition of claim 40, wherein the carbohydrate is selected from the group consisting of sugars, mono-, di-, tri-, oligo-, and poly-saccharides, and any physiologically acceptable derivatives, salts, forms, and solvates thereof, and any mixtures thereof.
42. (Previously presented) Composition of claim 39, wherein the second particulate material has a median volume diameter within the range 38 to 63 μm .
43. (Previously presented) Composition of claim 42, wherein the second particulate material has a median volume diameter within the range 45 to 63 μm .
44. (Previously presented) Pharmaceutical composition comprising a propellant and contained therein a particulate medicament comprising particles having a median

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aerodynamic diameter within the range 0.05 to 11 μm and a second particulate material comprising particles having a median volume diameter within the range 38 to 200 μm .

45. (Previously presented) Composition of claim 44, wherein the second particulate material is a carbohydrate.
46. (Previously presented) Composition of claim 45, wherein the carbohydrate is selected from the group consisting of sugars, mono-, di-, tri-, oligo-, and polysaccharides, and any physiologically acceptable derivatives, salts, forms, and solvates thereof, and any mixtures thereof.
47. (Previously presented) Composition of claim 44, wherein the second particulate material has a median volume diameter within the range 38 to 63 μm .
48. (Previously presented) Composition of claim 47, wherein the second particulate material has a median volume diameter within the range 45 to 63 μm .
49. (Previously presented) A mixture of first particulate material having a median aerodynamic diameter within the range 0.05 to 11 μm and a second particulate material having a median volume diameter within the range of 38 to 200 μm .
50. (Previously presented) Mixture of claim 49, wherein the second particulate material is a carbohydrate.
51. (Previously presented) Mixture of claim 50, wherein the carbohydrate is selected from the group consisting of sugars, mono-, di-, tri-, oligo-, and poly-

saccharides, and any physiologically acceptable derivatives, salts, forms, and solvates thereof, and any mixtures thereof.

52. (Previously presented) Mixture of claim 49, wherein the second particulate material has a median volume diameter within the range 38 to 63 μm .
53. (Previously presented) Mixture of claim 52, wherein the second particulate material has a median volume diameter within the range 45 to 63 μm .
54. (Previously presented) Composition of claim 44, wherein the first and second particulate materials are segregated upon aerosolization into a respirable first fraction and a non-respirable second fraction.
55. (Previously presented) Mixture of claim 49, wherein the first and second particulate materials are segregated upon aerosolization into a respirable first fraction and a non-respirable second fraction.